DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#10

JUN -6 1990

Re: Synarel
Docket No. 90E-0156

The Honorable Harry F. Manbeck, Jr.
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, DC 20231

Dear Mr. Manbeck:

This is in regard to the application for patent extension for U.S. Patent No. 4,234,571, filed by Syntex (U.S.A.) Inc., under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Synarel, the human drug product claimed by the patent.

The total length of the review period for Synarel is 3,180 days. Of this time, 2,725 days occurred during the testing phase and 455 days occurred during the approval phase. The periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 2, 1981.

   The applicant claims May 18, 1981 as the date the investigational new drug application (IND) for Synarel became effective. However, FDA records indicate that the IND became effective on June 2, 1981.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: November 16, 1988.

   The applicant claims November 22, 1988 as the date the new drug application for Synarel (NDA 19-886) was initially submitted. However, FDA records indicate that the application was received on November 16, 1988.

3. The date the application was approved: February 13, 1990.

   FDA has verified the applicant's claim that NDA 19-886 was approved on February 13, 1990.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Tom M. Moran, Esq.
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